Claims

1. A process for the preparation of a pharmaceutical composition comprising an active pharmaceutical ingredient capable of existing in multiple polymorphic forms, comprising a step of preparation of a wet phase comprising said active pharmaceutical ingredient and microcrystalline cellulose and liquid, wherein in said wet phase the weight ratio of active pharmaceutical ingredient to microcrystalline cellulose is above 1.0 and/or the weight ratio of active pharmaceutical ingredient to liquid is above 1.0.

2. A process according to claim 1 wherein said wet phase is an alcoholic phase and in said wet phase the weight ratio of active pharmaceutical ingredient to microcrystalline cellulose is above 1.0 and the weight ratio of active pharmaceutical ingredient to alcoholic liquid is above 1.0.

3. A process according to claim 1 or claim 2 wherein said weight ratio of active pharmaceutical ingredient to the liquid is above 2.0.

4. A process according to any preceding claim wherein said liquid is an alcoholic liquid consisting only absolute ethanol or of an aqueous ethanol solution.

5. A process according to any preceding claim wherein said microcrystalline cellulose is incorporated into the composition in more than one step.

6. A process according to any preceding claim wherein the active pharmaceutical ingredient is pravastatin sodium.

7. A process according to claim 6 wherein the liquid is ethanol and the weight ratio of pravastatin sodium to microcrystalline cellulose is above 1.0 and the weight ratio of pravastatin sodium to ethanol is above 2.0.

8. A process according to any preceding claim wherein the active pharmaceutical ingredient is crystalline pravastatin sodium having characteristic peaks in a X-ray diffractogram at 2θ of 4, 10,2, 16,3, 17,3, and 20,0 ± 0,2°.

9. A process according to claim 8 wherein the crystalline pravastatin sodium exhibits an X-ray diffraction pattern substantially similar to that in Figure 2 of US 6,740,775.

10. A process according to any of claims 6 to 9 whereby pravastatin sodium in a first polymorph form is stabilized against conversion into a polymorph form which exhibits broad peaks in X-ray diffraction pattern, having half-value widths of significant peaks above 2° 2 Theta.

11. A process according to any preceding claim wherein a binder is incorporated into the composition in a step other than the step of preparation of an alcoholic phase.

12. A process according to claim 11 wherein said binder is polyvinylpyrrolidone (PVP).

13. A pharmaceutical composition obtainable by the process of any preceding claim.

14. A stabilized pharmaceutical composition comprising the polymorph form of pravastatin sodium which exhibits X-Ray diffraction pattern with significant peaks having half-value widths below 2° 2 Theta characterized in that the polymorph form of pravastatin sodium is stabilized against converting into one exhibiting peaks in X-ray diffraction pattern, having half-value widths of significant peaks above 2° 2 Theta.

15. Use of a pharmaceutical composition according to claim 13 or 14 for the manufacture of a medicament for treatment of hypercholesterolemia.

16. A method of preventing or treating hypercholesterolemia in a susceptible patient, comprising administering to said patient a therapeutically effective amount of the pharmaceutical composition of claim 13 or 14.